K123243
1 of 2

510(k) Summary

APR 5 2013

Contact: Howard Schrayer
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Date Prepared: October 15, 2012

Device Trade Name: HEMOSTATIC BONE PUTTY 3
Resorbable Hemostatic Bone Putty

Manufacturer: Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533

Common Name: Bone wax

Classification: Unclassified

Product Code: MTJ

Indications for Use:

HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

Device Description:
HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty is a sterile, soft, moldable, biocompatible formulation comprised of water soluble and resorbable materials in a putty-like consistency intended for use in the control of bleeding from bone surfaces by acting as a mechanical barrier or tamponade. The putty is a mixture of alkylene oxide polymer-based materials, vitamin E acetate, granular calcium phosphate, and carboxymethylcellulose sodium salt. The material is virtually odorless, off-white in color and can be spread easily onto bone with minimal adhesion to surgical gloves. The bone putty does not require kneading prior to application.

Substantial Equivalence and Predicate Devices:
The device was shown to be substantially equivalent to previously cleared bone wax devices including Ostene® AOC Bone Wax (K041363), US Surgical Auto Suture Bone Wax (K971680), and Skeletal Kinetics CAAP (Calcium Apatite) Bone Wax (K111538), and traditional nonabsorbable bone wax devices, including CP Medical Bone Wax (K024372).

Performance Testing:
Bench testing, biocompatibility and animal functionality testing performed on the HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty demonstrate that the device is substantially equivalent to predicate devices in intended use, technological characteristics, and performance. This testing included the following:

Bench Testing was conducted to verify the device's handling properties, to characterize the device's performance over a range of temperatures and to evaluate the device's dissolution properties. The following bench studies were completed: relative stiffness, spreadability, stickiness, temperature sensitivity, electrocautery compatibility, dissolution and swelling.

Biocompatibility Testing was conducted to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-radiation sterilized device in accordance with GLP requirements: irritation, sensitization, acute systemic toxicity, genotoxicity, implantation/subacute toxicity, LAL and pyrogenicity.

Animal Testing included animal studies to demonstrate intraoperative *in vivo* hemostasis, resistance to irrigation, ability to remove the device, and to characterize absorption time.

Conclusion
HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty is substantially equivalent to previously cleared and preamendment bone wax devices with respect to intended use, general technological characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Orthocon, Inc.
% Mr. Howard Schrayer
One Bridge Street, Suite 121
Irvington, New York 10533

Letter dated: April 5, 2013

Re: K123243
Trade/Device Name: Hemostatic Bone Putty 3 Resorbable Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: March 11, 2013
Received: March 12, 2013

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123243

Device Name: HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty

HEMOSTATIC BONE PUTTY 3 Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123243